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(71) Applicant *(for all designated States except US)*: ALK ASSOCIATES [DK/DK]; Hesselbjerg 1, DK-5700 Svendborg (DK).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: AL-KASSIM, Adil [DK/DK]; Strandvaenget 10, DK-5700 Svendborg (DK).

(74) Agent: BROCK-NANNESTAD, George; Sludebakken 1, DK-5800 Nyborg (DK).

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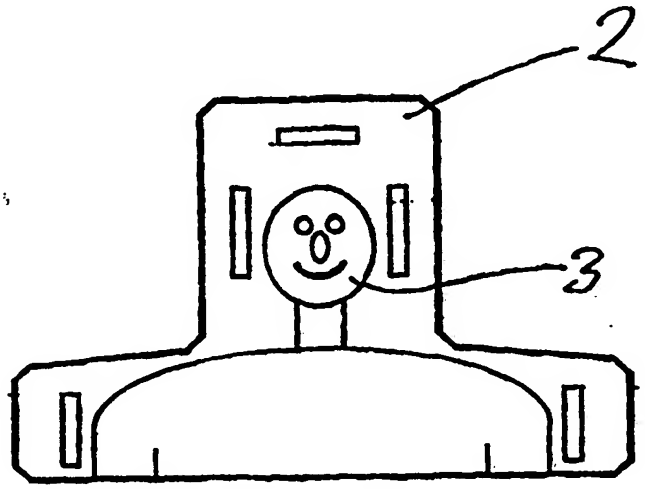
(54) Title: A THERMOPLASTIC SHEET WITH EDGE PARTS

(57) Abstract

Immobilisation for radiation treatment is performed by means of low-temperature thermoplastic sheets individually adjusted to the patient. The edges are secured to the top of the treatment table by complex fixtures. The invention provides a simple means to obtain reliable connection between heat-tolerant edge parts and the thermoplastic material. The edge parts grip and deform the edge during the heating, and adhesion and cooling secure the grip.



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A thermoplastic sheet with edge parts

The invention relates to a low temperature heat mouldable thermoplastic sheet with profiled edge parts for use in immobilization.

Low temperature thermoplastic materials are currently used in fixation applications such as in making orthopedic splints and in the immobilization of various body parts of patients undergoing radiation therapy treatment. The use of such thermoplastic materials is not restricted to these applications and is/can be used in various other applications where fixation or immobilization of a volume is required.

Such thermoplastic materials are usually formed as sheets, strips or rods. They may or may not be perforated. The perforation percentage/hole size varies and the they may have various thicknesses of up to 6 mm or more. Such thermoplastic materials softens when heated to approximately 45 °C or above and normally become fully soft in the temperature range 60 - 80 °C. In practical use these materials may be placed in an oven or a water volume heated to the softening temperature of the material. As the material is heated by the water it softens and becomes pliable/formable. The material is then removed from the water, placed and formed around the volume required to be immobilized. As the material cools down to room temperature, it solidifies retaining its formed shape.

Although thermoplastic materials are applied in various fields for fixation and immobilization purposes, as an example the application described here is the immobilization of any certain volume/volumes of the human body of a patient undergoing radiation therapy treatment. The immobilization takes place during the planning stage, the patient preparation stage and during the actual irradiation treatment time.

The need of immobilization arises from the requirement to irradiate specific sections/volumes of the human anatomy decided by the treatment group. These

sections/volumes are determined from a detailled medical investigation which may well include X-ray, CAT and other imaging techniques. As a result of the investigation a treatment is planned normally with the aid of a sophisticated treatment planning computer. In treatment planning, factors such as dose level and duration, the volume to be irradiated, the number of treatment sessions, angle/angles of irradiation are determined. The patient will then be positioned on a treatment simulating apparatus (the simulator, which is a machine that has all the parameters/movements of a treatment machine but excluding the high energy radiation), positioned in the correct treatment position and all the treatment parameters controlled. From then on the patient goes, in a session, to the treatment apparatus (the accelerator) where, each time, he is re positioned exactly in the same position according to the treatment plan and irradiation takes place. This procedure is repeated each time a patient is treated.

From above we observe that accurate repeatable positioning and re-positioning of the patient at each treatment is of fundamental importance and influence. Although the treatment is planned/calculated to a very high precision and although it is possible to re-position the patient (via the positioning devices of the accelerator) very accurately, patient movement (including involuntary movements such as those related to breathing, swaying, etc.) are present and must be accounted for. This presents the need for patient immobilization during treatment.

Various immobilization techniques have been devised and are today in use. The main ones are:

1. vacuum forming of high temperature thermoplastics on a gypsum or a two component polyurethane replicas of the patient (VFHT).

2. direct forming of low temperature thermoplastics on the patient (DLT).

In VFHT, the patient is positioned in the treatment position, a replica of the patient's volume which is to be immobilized is made by moulding of either gypsum or a two component plastic curing foam on the volume. When cured and set this replica will be used as a form into which a high melting point thermoplastic sheet is vacuum formed. When the vacuum formed sheet cools down it retains the shape of the replica and the patient as a mask. The mask is attached to the treatment table via a mask holder which normally consists of a plastic or carbon fiber plate that can be attached to the treatment table and also allows the mask to be attached to. Various attachment mechanisms are used to connect the mask to the mask holder. The disadvantage of this technique is its labour intensive procedure, inaccuracies that may well occur due to making the replica and thereafter making the immobilizing mask and the difficulty of correcting an error or unfitting section of the mask at a later stage during the treatment.

In DLT the patient is positioned in the treatment position on a support, such as a table. A mask holder containing attachment means to the table and attachment means to the mask is placed between the treatment table and the patient where the irradiation is required. Alternatively, the attachment means are separate from the mask holder or integral to the table. A low temperature thermoplastic sheet with attachment means to the mask holder is heated to its softening temperature (usually approximately 65 - 70 °C and usually in a heated water bath). When fully soft, the sheet is transferred to the patient, placed over the volume which is to be immobilized, contoured around the volume and fastened to the mask holder via the attachment means on the low temperature thermoplastic sheet and the mask holder.

Various types of attachment means and mechanisms

are used to provide the attachment and detachment of the mask from the mask holder. The following are examples of attachment:

- a mask holder with attachment pins permanently provided at each side such that when the softened thermoplastic sheet is pressed against the pins holes of a similar diameter to the pin are created in the thermoplastic sheet. These holes will retain their shape and position when the material cools down to room temperature and provide the attachment means to the mask holder each time the patient is positioned for treatment. Locking bars may be used to firmly prevent the thermoplastic sheet from sliding away from the pins by sandwiching the sheet from both sides.

- a mask holder with attachment means such as swivel clamps or self locking pins which permits locking edges of the thermoplastic sheet to the mask holder.

- a mask holder with attachment means such as swivel clamps or self locking pins which permits locking of temporarily attached edges/extensions of a high melting temperature material to the thermoplastic sheet, to the mask holder.

- a mask holder with slots/recesses providing a cavity into which bent edges of the thermoplastic material can be inserted and secured into position.

It is a purpose of the invention to avoid the disadvantages described, whereby the low-temperature thermoplastic sheet shall be more efficiently fastened as regards to precision, reproducability, and simplicity.

The invention is solved in conjunction with the characteristics of the low temperature mouldable thermoplastic sheet indicated in the introduction in that the edge parts consist of profiled liners in a material which does not deform under working temperature, having a shape which may interlock with a slot in the attachment fitting, which edge parts are permanently

joined to the heat mouldable thermoplastic sheet. According to the present invention, a high melting temperature profile is permanently attached, during manufacture, to a low melting point thermoplastic material such that when the low temperature thermoplastic material together with the high melting point profile are subjected to a heating medium at temperature sufficient to soften up the low temperature thermoplastic material and render it pliable, the high melting temperature profile retains its form and dimensions and can be used to attach the low temperature thermoplastic material into recesses/slots manufactured in a mask holder.

In an advantageous embodiment the profile is made of a high temperature thermoplastic material and formed in an L shape where the lower/horizontal part of the L is used to fit into the slots of the mask holder while the higher vertical section of the L is used to permanently attach the profile to the low temperature thermoplastic sheet.

In a further advantageous embodiment the higher vertical section of the L profile contains a U form where the low temperature thermoplastic sheet may be inserted into the opening of the U having a gap suitable to the thickness of the low temperature thermoplastic sheet. Additionally, one or both internal walls of the U portion may have sharp ridges to be in contact with sides of the low temperature thermoplastic sheet when the later is inserted into the U opening. Such ridges will provide penetration through the sides of the low temperature thermoplastic sheet when the low temperature thermoplastic sheet softens while the high temperature profile remains solid. This penetration will enhance the permanent contact between the profile and the sheet. Furthermore, low temperature thermoplastic materials are tacky when soft and strongly bond to various other materials such as various types of high temperature

thermoplastic material. Choice of adhesion compatibility between the low temperature thermoplastic material and the high temperature profile material will result in further adhesion and permanent contact between the sheet and the profile. Chemical/UV or electron beam curing adhesives may also be used to bond the profile to the sheet during manufacture.

Another embodiment of the invention is represented by a slit in the low-temperature thermoplastic material which in use surrounds a part of the edge profile, thereby creating a larger area of attack.

In large-scale industrial manufacture of the joint between the low-temperature thermoplastic material and the heat-resistant edge material, strip welding of the joint may be advantageously performed.

The invention will be described in detail with reference to the drawings, in which

Fig. 1 shows a general view of a radiation treatment accelerator,

Fig. 2 shows a longitudinal section through a treatment table with a patient,

Fig. 3a shows a mask holder from above,

Fig. 3b shows a mask holder with a patient in place,

Fig. 4 shows the cross section of a profiled liner according to the invention,

Fig. 5 shows a configuration of a mask holder for use with the profiled liner according to the invention, and

Fig. 6 shows a different configuration.

Fig. 1 shows the general layout of an accelerator in order to give an example of the environment in which the present invention may be used. In Fig. 2 is shown a more detailled layout in schematic form, and the precision which is referred to in the introduction of the specification is here related to a specific placement of a patient 1.

In Fig. 2 is shown that the treatment is intended for a chest volume, but the head and neck area may be a target in a different situation, and this is shown in Fig. 3a and 3b which shows a mask holder 2 which is used to immobilize the upper part of the body including the head 3. The mask holder 2 is shown as a separate appliance which is fitted to the table, however its relevant attachment parts may be formed directly in the table itself. These attachment parts are slots 4 which are distributed in such a manner that the immobilization is effective against movement when the mask is fitted. The slots 4 are undercut in the present embodiment.

Fig. 4 shows an embodiment of the invention according to claim 4 and is shown in enlargement. A generally L-shaped edge part 5 has a longer side 6 for joining with the low temperature heat mouldable sheet and a shorter part 7 for engaging the slots 4 of the mask holder or in the table. On the side 6 is provided a U-shaped part 8 which defines a narrow passage 9 which serves to receive the low temperature heat mouldable sheet. During manufacture the sheet would be pressed into the passage 9 while cold and hence stiff, and the prong 10 of the U will flex outwards in order to accommodate the thickness of the sheet. The ridges 11 in the prong will provide some grip, but upon heating of the sheet and edge part 5, the low temperature heat mouldable sheet flows, and the ridges 11 work themselves into the sheet at same time as the prong 10 moves slightly inwards again. This heating is ideally performed during manufacture but may also be performed at the first heating of the sheet for forming a mask. Simultaneously adhesion between the edge part 5 and the sheet occurs, and the joint between the sheet and the edge part becomes very secure indeed. The fact that a large part of the sheet and generally the whole thickness (cross section) participates in the joint makes this construction very stable. In principle it is

also possible to use a sheet which is thicker than the narrow passage 9 of the U, if it is heated before insertion when it will flow somewhat and permit the ridges 11 on the prong to grip and squeeze this thicker sheet. The ridges which extend perpendicular to the U-profile are sawtooth shaped, as may be seen in Fig. 4. However, manufacturing requirements may decide to use other shapes, and even a large number of distributed individual protrusions will achieve the desired gripping.

The stability obtained by the invention enables proper use to be made of high precision attachment fittings in the mask holder or in the table. High precision is obtained by using a lenght of edge part 5 which corresponds closely to the lenght of the slot 4, and by using a thickness of the part 7 of the L which corresponds closely to the space under the overhang of the slot 4. Then the L-shaped edge part 5 may be locked very precisely into the slot 4 by a locking block or wedge which is inserted subsequently to the L-shaped part 5 as shown schematically in Fig. 5 a) and b). The slot 4 in the mask holder 2 has a width 12 which is only a little larger than the lenght of the part 7 of the L-shaped edge part 5 a locking device in the form of a block or wedge 13 is fitted in the opening which defines a remaining width 14 of the slot which is essentially identical to the thickness of the part 6 of the L-shaped edge part 5 near the bend. Hence movement in and out of the edge part with respect to the mask holder 2 is completely avoided. Similarly, the thickhess of the overhang 15 of the mask holder 2 is such that the part 7 of the L-shaped edge part 5 may only be slid into it without any play, and when the block 13 is fitted in place, the edge part will with great precision assume exactly the same position it had on previous occasions, and will have on later insertions. The mask holder 2 is fixed to the table by means which are not shown.

In Fig. 6 a similar construction is shown, the only difference being that the mask holder 2 has its own closed bottom of the slot 4 and is not dependent on the surface of the table for its precision. In a similar way the table itself may have a series of slots or recesses for attachment of the L-shaped edge parts 5.

The slots or recesses need not have complete overhang but may be fingers only, and the locking device need not be of the same lenght as the slot, but may be shorter pieces. The exact choice will be determined by considerations of cost, strenght, and ease of cleaning.

PATENT CLAIMS

1. A low temperature heat mouldable thermoplastic sheet with profiled edge parts (5) for use in immobilization, said edge parts cooperating with attachment fittings in or on the element (2) to which the sheet is to be attached characterized in that the edge parts (5) consist of profiled liners in a material which does not deform under working temperature, having a shape which may interlock with means, in particular a slot (4), in the attachment fitting (2), which edge parts (5) are permanently joined to the heat mouldable thermoplastic sheet.

2. A sheet according to claim 1, characterized in that the profiled liners have an L-shape, one part of which is joined to the heat mouldable sheet, the other part cooperating with the slot.

3. A sheet according to claim 1 and 2, characterized in that the profiled liner engages essentially the whole cross section of the heat mouldable thermoplastic sheet.

4. A sheet according to claim 3, characterized in that the part of the profiled liner engaging the heat mouldable sheet is provided with a U-shaped part (8) with an opening (9) corresponding to the sheet into which the sheet edge is fitted and is gripped tightly.

5. A sheet according to claim 4, characterized in that the inner wall of at least one prong (10) of the U-profile has protrusions in the shape of ridges, ribs, steps, knobs or the like, which grip into the low-temperature thermoplastic material, whereby in particular the U-profile is arranged suoh that it creates a durable connection by deformation against the restitution force of the U-

profile and subsequent penetration into the softened thermoplastic material.

6. A sheet according to claim 4 or 5, characterized in that a bead of curing resin, such as a heat, UV or electron beam radiation curing resin, or a chemically curing resin is interposed and cured between the heat mouldable thermoplastic sheet and a face of the profiled liner.

7. A sheet according to any of the claims 2 to 4, characterized in that the side of the profiled liner is strip welded to the side of the sheet near the border.

8. A sheet according to any of the claims 2 to 4, characterized in that the edge of the heat mouldable sheet is slit, and that the profiled liner is fitted into the slit and fastened.

9. A sheet according to any of the claims 2 to 7, characterized in that the L-shaped profiled liner(s) matches closely with the attachment fitting in the form of a mask holder, both as regards the thickness of the profiled liner(s) and its (their) lenght, the slots of the mask holder being supplied with retaining protrusions which define spaces corresponding closely to said thickness and lenght.

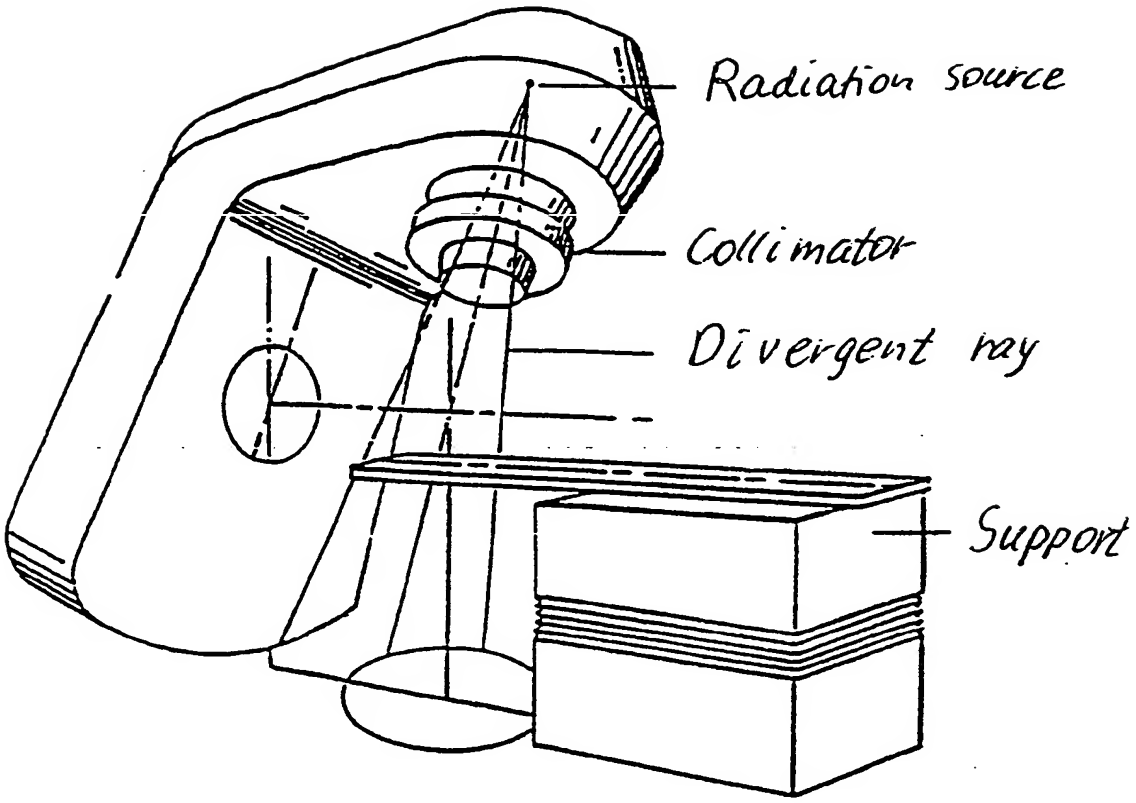

Fig. 1

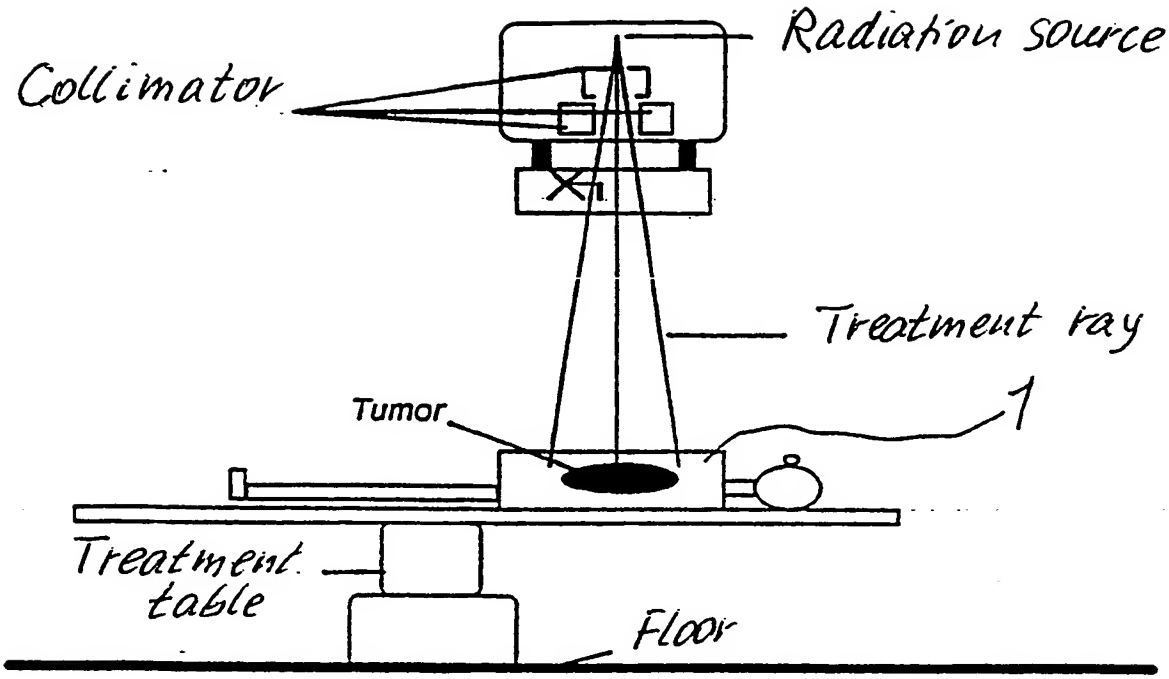

Fig. 2

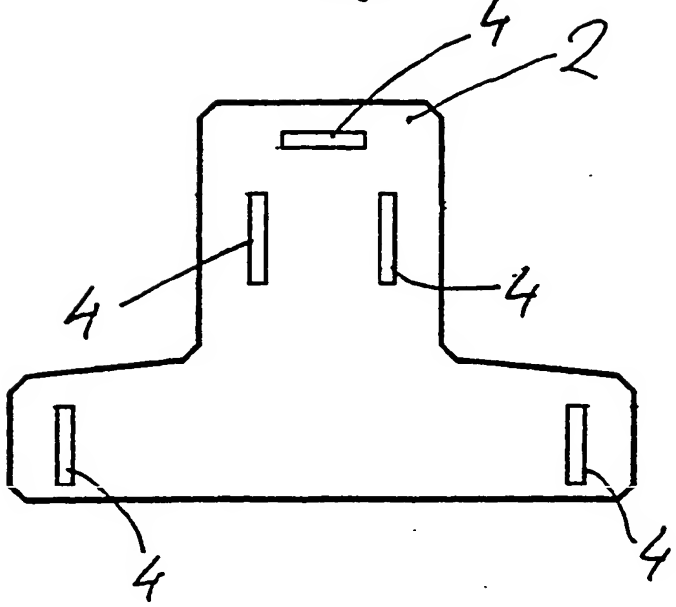

Fig. 3a

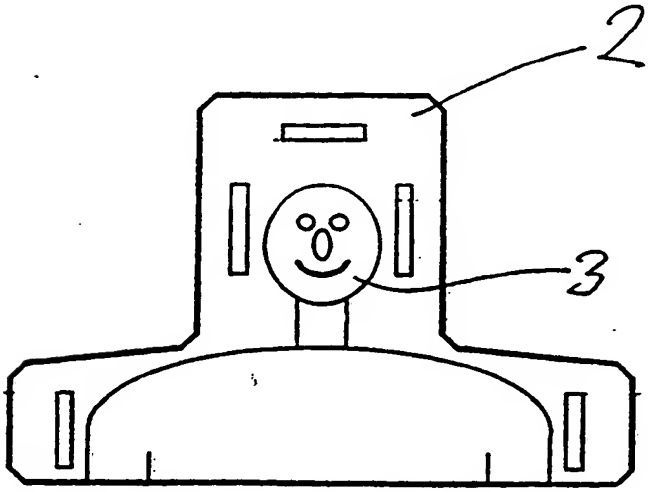

Fig. 3b

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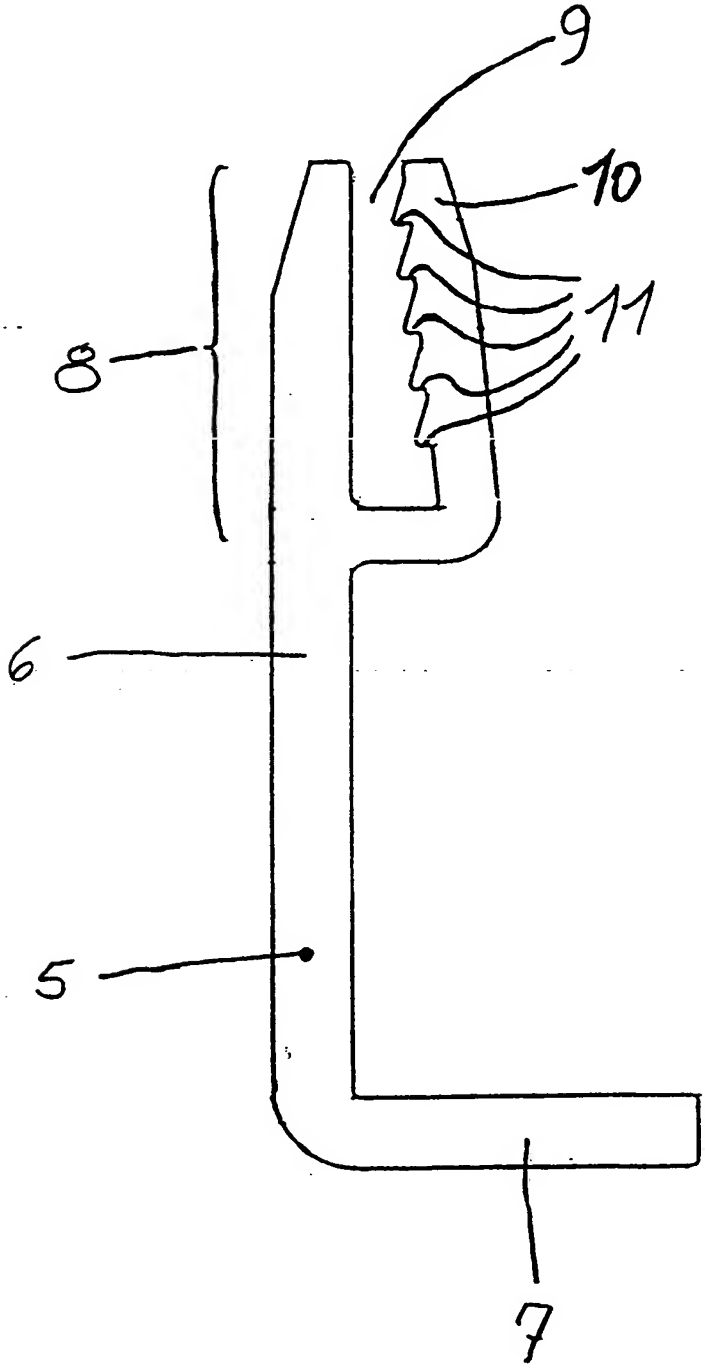

Fig. 4

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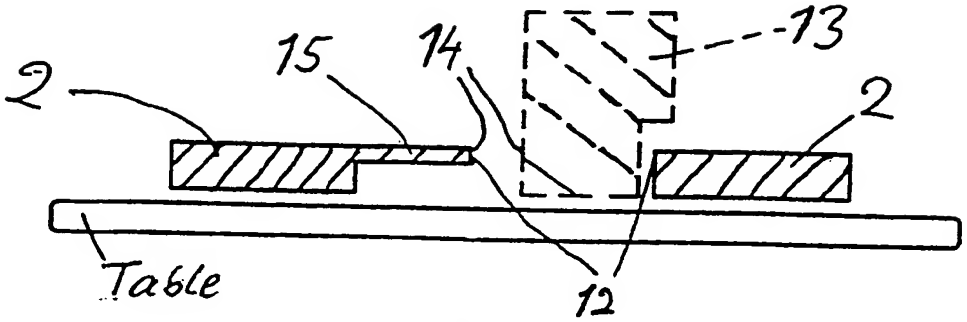
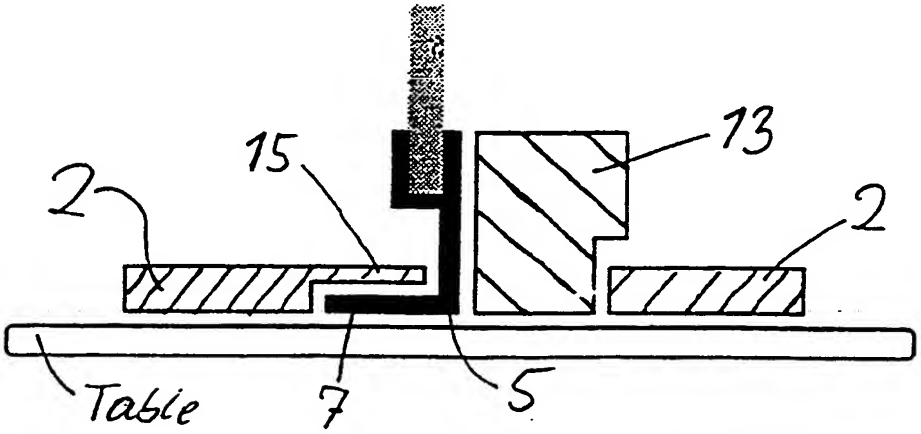


Fig.5 a)



b)

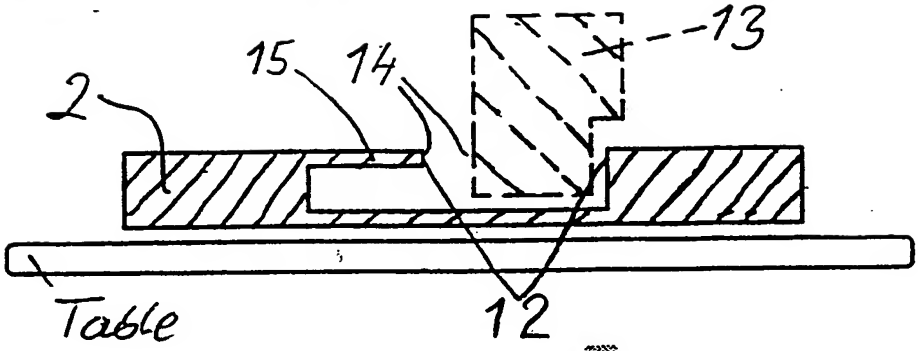
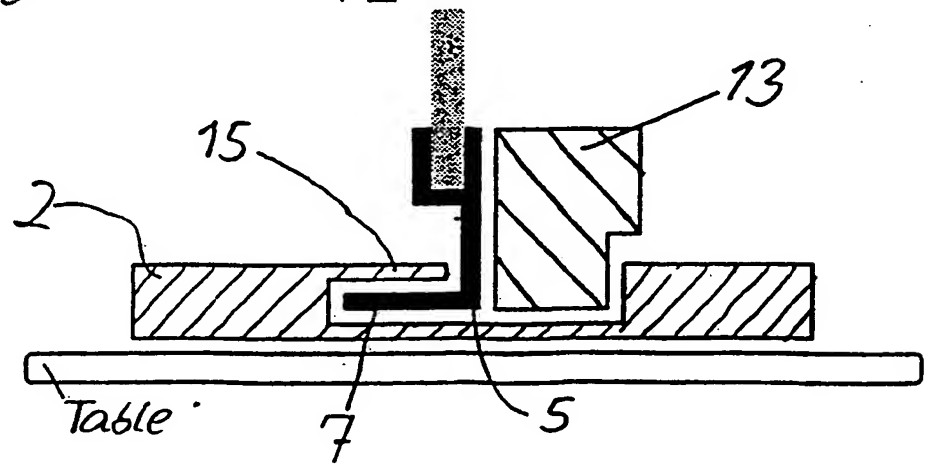


Fig.6 a)



b)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 96/00310

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: B29C 51/42, A61B 6/04
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CA 970903 A (KLIEVER, WALDO H.), 15 July 1975 (15.07.75), page 7, line 28 - line 31; page 9, line 22 - line 24, figure 4	1
A		2-9
A	EP 0728446 A1 (THE CLEVELAND CLINIC FOUNDATION), 28 August 1996 (28.08.96)	1-9

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 November 1996	12 -11- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Ingrid Falk Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Information on patent family members

28/10/96

International application No.
PCT/DK 96/00310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CA-A- 970903	15/07/75	BE-A- 778733	16/05/72
		DE-A- 2204283	07/09/72
		FR-A- 2124976	22/09/72
		NL-A- 7201091	03/08/72
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